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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,282	12/06/2001	Thomas W. Konowalchuk	LFT000 CIP3	4202

7590 04/21/2004

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,282	KONOWALCHUK ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed December 15, 2003 have been entered.

Claims 1-26 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-14, 16-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US Patent 5,385,938) in view of Poli et al. (Food Chemistry, 1979; 4(3): 251-258), Wenninger (International Cosmetic Ingredient Dictionary and Handbook, 7th ed., Vol. 1, page 163-168), and Merck Index (11th ed., 1989, Glycolic acid monograph 4394, page 4399).

Yu et al. teaches a topical composition with glycolic acid is the active and about 12.4% ethanol as solvent (See col. 14, Example 1). Yu et al. also teaches that the composition has pH of 3.0 (See col. 14, Example 1). Yu et al. also teaches that the glycolic acid composition is useful to eradicate lesions such as warts, which is a viral infection of papallomas virus (See col. 30, line 10 – col. 31, line 2). Yu et al. also teaches that other pharmaceutically acceptable vehicles other than water and ethanol may be used (See col. 13, lines 11-13). Yu et al. also teaches that the concentration of hydroxyacids, including glycolic acid, may range from 0.02 to 12M (See col. 13, lines

17-19). Yu et al. also disclosed that the amphoteric compounds are not necessarily present in the composition of Yu et al. in order to have antiviral activities (See col. 11, lines 55-59). Yu et al. also teaches that the composition may be formulated into gel, ointment, cream, lotion, and other cosmetic and pharmaceutical preparation (See col. 13, lines 4-6).

Yu et al. does not expressly teach 1,3-butanediol, as known as butylenes glycol, is useful as pharmaceutical vehicle. Yu et al. does not expressly teach that the glycolic acid containing topical composition as useful in the prophylaxis of lesions caused by viruses within the Herpesvirdae. Yu et al. does not expressly teach the composition having a specific pH of 2.45. Yu et al. does not expressly teach the concentration of glycolic acid in the composition as 0.6%.

Poli et al. teaches that glycolic acid is virucidal against herpevirus (See particularly page 253, Table 1).

Wenninger teaches that butylenes glycol as useful as solvent in numerous cosmetic marketed products (See page 163-168).

Merck Index teaches that the pH 0.5% of glycolic acid solution as 2.50 (See the glycolic acid monograph). Examiner notes that 0.5% of glycolic acid is about 0.31M.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the glycolic acid containing topical composition, in the prophylaxis of lesions caused by viruses within the

Herpesvirdae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate 0.6% of glycolic acid to the herein claimed prophylactic method.

One of ordinary skill in the art would have been motivated to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45 because butylenes glycol is known to be useful in cosmetic products as solvent. Employing any known solvents, including butylene glycol, into a topical composition would have been reasonably expected to be useful in formulating a topical wart-treating composition and treating the same. Moreover, the optimization of result effect parameters (e.g., pH of the composition and the amount of active (glycolic acid)) is obvious as being within the skill of the artisan since 0.31M is within the range disclosed in Yu et al., absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ the glycolic acid containing topical composition in the prophylaxis of lesions caused by viruses within the Herpesvirdae. Based on the teachings of Poli et al. and Yu et al., glycolic acid is known to be effective in killing herpes virus. Therefore, applying a glycolic acid composition to reduce the number of herpes viruses, and thereby reducing the chances for herpes viruses to cause the lesions, would have been reasonably expected to be effective.

Claims 1, 7-8, 15, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al. (Indian Journal of Animal Sciences 1998; 68(6): 518-

520, reference of record) in view of Disinfectant Drugs (Therapeutic Products Programme Guidelines published by Health Canada, April 1999, pages 42-45) and Remington (Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 218-219 and1314-1315).

Bhatia et al. teaches that 0.4N hydrochloric acid is effective in inactivating sheep pox virus (See particularly page 519, col. 1, Table 1 and col. 2, third paragraph). Bhatia et al. also teaches that the "Ranch" strain of goat pox virus is more sensitive in acidic pH 3.0 as there was 5 log fall in the titer in the acidic pH (See page 519, col. 2, third paragraph).

Bhatia et al. does not expressly teach the use of hydrochloric acid with an alcohol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, in the method of prophylaxis of lesions caused by Poxviridae such as molluscum contagiosum. Bhatia et al. does not expressly teach the pH of the composition as 2.45.

Disinfectant Drugs teaches isopropanol 15% or above is effective as a single medicinal ingredient for disinfecting contact lens (See page 43, Table).

Remington teaches that isopropanol is a very good pharmaceutical solvent, which is comparable to ethanol (see page 219, col. 1). Remington also teaches that ethanol is a very good pharmaceutical solvents (See page 1314, col. 2 – page 1315, col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate isopropanol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, with hydrochloric acid in a method for the prophylaxis of lesions

caused by Poxviridae such as molluscum contagiosum. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the pH of the composition to 2.45.

One of ordinary skill in the art would have been motivated to incorporate isopropanol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, with hydrochloric acid in a method for the prophylaxis of lesions caused by Poxviridae such as molluscum contagiosum because isopropanol is known to be useful as both a solvent and a disinfectant and hydrochloric acid is known to have virucidal activities against pox viruses. Employing hydrochloric acid in a method of prophylaxis of lesions caused by pox viruses, such as molluscum contagiosum, would have been reasonably expected to be effective. Incorporating a well-known commonly used pharmaceutical solvent, such as isopropanol, into a topical formulation and optimizing the amount of such solvent used for the same purpose would be obvious as being within the purview of skilled artisan. Moreover, adding a secondary disinfectant such as isopropanol to control the secondary infection which may be accompanied by the outbreaks or lesions caused by such virus infection would also be reasonably expected to be useful. Furthermore, optimization of the pH to 2.45 would be considered obvious as being within the purview of skilled artisan.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d

1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the data in page 9, 10, 14-16 has been considered, but are not found persuasive. The data merely demonstrates the upper limit of effective pH for virucidal activities. Please note that the pH of the composition mainly depend on the amount of acids present in the composition. Therefore, the data regarding the pH limitation is considered as a reflection of what the effective amount of glycolic acid required in order for the composition to be virucidal (See page 10 of the instant specification, Tables 2 and 3). This is seen to be an expected effect based on the cited prior art. No convincing and clear unexpected result is seen.

Response to Arguments

Applicant's rebuttal arguments filed December 15, 2003 averring the amphoteric compounds, which are required to be in the composition in order to produce an pH of 2.45, being excluded by the claims as amended have been considered, but are not found persuasive. The claims herein are given the broadest reasonable interpretation. The herein claimed method of prophylaxis of viral infection employs a composition having an alcohol and an acid. Although in the pH of the particular example of Yu without the pseudoamphoteric compound is 1.9, Yu teaches the effective amount of glycolic acid can be in the range of 0.02 to 12M (See col. 13, lines 17-19). As

discussed in the rejections above, when the concentration of glycolic acid is about 0.31 M, the pH is about 2.5, which falls within the herein claimed range. Moreover, Yu et al. clearly disclosed that the amphoteric compounds are not necessarily present in the composition of Yu et al. in order to have antiviral activities (See col. 11, lines 55-59). The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics

of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.") (See MPEP 2111.03).

Applicant's rebuttal arguments file December 15, 2003 averring the cited prior art's failure to teach glycolic acid as effective in prophylaxis for lesions caused by herpes virus, have been considered, but are not found persuasive. Although the cited prior art not expressly teaches the prophylaxis effectiveness, based on the teachings of Poli et al. and Yu et al., glycolic acid is known to be effective in killing herpes virus. Therefore, applying a glycolic acid composition to reduce the number of herpes viruses, and thereby reducing the chances for herpes viruses to cause the lesions, would have been reasonably expected to be effective.

Applicant's rebuttal arguments file December 15, 2003 averring the cited prior art's failure to provide motivation to incorporate 1,3-butanediol into the herein claimed method, have been considered, but are not found persuasive. 1,3-butanediol is known as a commonly used solvent for pharmaceutical use. Incorporating such commonly used solvent in pharmaceutical art into the pharmaceutical composition of Yu for treatment or prophylaxis of viral infection would be obvious as the selection of one or another commonly used solvent would be seen as a simple selection from among obvious alternatives.

Applicant's rebuttal arguments file December 15, 2003 averring the cited prior art not teaching the critical features of the herein claimed invention have been considered,

but are not found persuasive. As discussed above, the claims herein are given the broadest reasonable interpretation and thus, the herein recited method of prophylaxis lesions caused by herpes or pox viral infection employing a composition having an alcohol and an acid. As discussed above, the cited prior art clearly renders the herein claimed invention obvious.

Applicant's rebuttal arguments file December 15, 2003 averring the cited prior art's failure to provide motivations or suggestion to combine isopropanol and hydrochloric acid have been considered, but are not found persuasive. The motivation lies in that hydrochloric acid is known to be effective in against goat-pox virus and isopropanol is a well-known solvent and disinfectant. Combining these two agents for very same purpose would be obvious, absent evidence to the contrary.

Applicant's rebuttal arguments filed December 15, 2003 averring Bhatia not teaching the herein claimed method of prophylaxis for lesions caused by herpes and/or pox viral infection have been considered, but are not found persuasive. Although the cited prior art not expressly teaches the prophylaxis effectiveness, based on the teachings of Bhatia et al., hydrochloric acid is known to be effective in killing pox virus. Therefore, applying a hydrochloric acid composition to reduce the number of pox viruses, and thereby reducing the chances for pox viruses to cause the lesions, would have been reasonably expected to be effective.

Applicant's rebuttal arguments filed December 15, 2003 averring Bhatia merely teaching the *in vitro* employment of hydrochloric acid and isopropanol to kill goat-pox viruses and therefore, not suggest the herein claimed method of prophylaxis for lesions

caused by herpes and/or pox viral infection have been considered, but are not found persuasive. Since both hydrochloric acid is known to be effective in against goat-pox virus and isopropanol is a well-known solvent and disinfectant, the employment of both agents would have been reasonably expected to exert the very same antiviral effect, and thus, useful as effective prophylaxis of pox viruses thereby.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617